REMARKS

Claims 164, 177, 284-288, 290, 292, 293, 295 and 307-328 are pending. Claims 164, 177 and 307-309 have been amended and Claims 284, 285, 287, 288, 290 and 293 have been canceled without prejudice and without intending to publicly dedicate any patentable subject matter. New Claims 310-328 have been added. Support for the amendments can be found in Example 10, pages 74-75 of the Specification as well as on pages 12 and 13 of the Specification. No new matter has been added by these amendments.

Rejection Under 35 U.S.C. § 112, first paragraph

The Examiner maintains the rejection of Claims 164, 177, 221, 231, 285, 287-290, 293, 297, 300 302 and 305 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically the Examiner contends that there is insufficient written description to demonstrate that the Applicant was in possession of the entire class of antibodies specific for "cysteinylated" proteins.

For the reasons discussed in Applicants' previous response, Applicants contend that they have provided more than sufficient disclosure to establish that they did, in fact, have possession of the entire scope of the claimed invention of the rejected claims as of the filing date of the present application. However, solely in the interests of advancing prosecution, Applicants have limited Claim 164, and claims depending therefrom, to an isolated antibody that specifically binds to a cysteinylated albumin protein. Support for this amendment is found at least in Example 10 of the Specification. In addition, Applicants have canceled Claims 284, 285, 287, 288, 290 and 293.

For the foregoing reasons, Applicants respectfully request withdrawal of this rejection 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C § 102(b)-Doyen et al as evidenced by Glowacki et al

The Examiner has maintained the rejection of Claims 164 and 284-285 under 35 U.S.C. §102(b) as being anticipated by Doyen et al., (*Mol. Immunol.*, volume 22, pages 1-20 (1985)) "as evidenced by" Glowacki et al. *(J. Biol. Chem.*, volume 279, pages 10864-10871 (2004).[1] It is the Examiner's position that:

> Doyen et al. teach monoclonal antibodies specific for human serum albumin. . . . [C]ysteinylated albumin is identical to albumin, except for the presence of a disulphide bonded cysteine residue at amino acid residue 34 [("Cys 34")]. Therefore, the antibodies taught by Doyen et al. would inherently bind to cysteinylated albumin, since it comprises an identical amino acid sequence to albumin . . . .

Applicants respectfully traverse this rejection.

Applicants have amended Claim 164 to recite an isolated antibody that specifically binds to a cysteinylated albumin protein and have canceled Claims 284 and 285. Contrary to the Examiner's contentions, Doyen et al. does not inherently anticipate the claims when the proper standard is applied.

The standard for inherent anticipation is quite clear. While inherent or implicit disclosures within references may be used to support rejections under 35 U.S.C. § 102, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP § 2112 (IV) (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)) (emphasis in original). "Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Thus when a claim limitation is not explicitly set forth in a reference, the extrinsic evidence must make clear that the characteristic is necessarily and inevitably present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re*

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[1] It is noted that Glowacki et al. is not prior art to the present application. However, for the purpose of responding to the present Office Action only, Applicants will consider that the Examiner's reliance on Glowacki et al. to be proper.

Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). Additionally, anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references." *W.L. Gore v. Garlock, Inc.*, 721 F.2d at 1554 (Fed. Cir. 1983). Inherency, therefore, may not be established by probabilities or possibilities, but only by a characteristic that is always present in a product or occurs each and every time a process is carried out. *Robertson, supra*, at 1950-51. The burden falls on the Examiner to provide a basis in fact and/or technical reasoning to support the assertion that the inherent property necessarily flows from the prior art. *Ex Parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

As noted by the Examiner, cysteinylated albumin has a disulfide-bonded cysteine residue at amino acid residue 34, whereas non-cysteinylated albumin does not contain this disulfide bonded cysteine. Thus, an antibody directed toward non-cysteinylated albumin may not bind cysteinylated albumin, as such antibodies may specifically recognize and bind to an epitope including Cys 34 that is not cysteinylated. Conversely, an antibody directed toward cysteinylated albumin may not bind to non-cysteinylated albumin, as such antibodies may specifically recognize and bind to an epitope including Cys 34 that includes an additional cysteine residue through a disulfide bond. Quite clearly, the requisite degree of certainty to establish inherency is not present.

Accordingly, Applicants assert that none of the antibodies described in Doyen et al. are taught, expressly or inherently, to bind specifically to a cysteinylated albumin protein and thus Doyen et al., does not anticipate the pending claims, as amended.

In view of the foregoing, it is respectfully submitted that Claim 164, and claims depending therefrom are allowable and Applicants respectfully request withdrawal of this rejection.

Rejection Under 35 U.S.C § 103(a)-Doyen et al as evidenced by Glowacki et al, in view of US Patent 5,198,340

The Examiner has maintained the rejection of Claims 164, 177, 221, 231, 284-285, 287-291, 293, 297-298, 300, 302-303 and 305 under 35 U.S.C. 103(a) as being unpatentable over Doyen et al. and Glowacki et al. in view of U.S. Patent No. 5,198,340. The Examiner states that Doyen et al and Glowacki et al do not teach a kit comprising the albumin-specific antibody while the '340 patent teaches ". . . antibodies for immunological detection assays can be packaged in the form of a kit". Applicants respectfully traverse this rejection for the reasons discussed in response to the rejection under Doyen et al. and Glowacki et al. above. Specifically, Doyen and Glowacki do not teach an antibody that specifically binds to a cysteinylated albumin protein and the teachings of the '340 patent do not remedy this deficiency. Therefore, the cited references, alone or in combination, do not teach or suggest kits containing antibodies that bind selectively to a cysteinylated albumin protein. Accordingly, Applicants request that this rejection be withdrawn.

Rejection Under 35 U.S.C § 102(e)-US Patent Publication 2003/0124616

______The Examiner has rejected Claims 164, 177, 284, 285, 287, 288, 290, 293 and 307-309 under 35 U.S.C. 102(e) as being anticipated by US Patent Publication 2003/0124616. The Examiner asserts that the '616 publication teaches detecting homo-cysteinylated proteins in a sample, that the proteins can be detected using an antibody that specifically binds to the homo-cysteinylated proteins, that the homo-cysteinylated protein can be albumin and that the '616 publication teaches a kit comprising said antibodies.

Applicants have amended Claim 164 (and dependent Claims 177 and 307-309) to recite an isolated antibody that specifically binds to a cysteinylated albumin protein. In addition, Applicants have canceled Claims 284, 285, 287, 288, 290 and 293.

Of course, a cysteinylated albumin protein is not the same as a homocysteinylated albumin protein. See, for instance, paragraphs [0033] and [0035] through [0041]. Further, the ‘616 publication discloses only antibodies that can be used to detect the presence of homocysteinylated transthyretin (see, for example, paragraph [0043] of the ‘616 publication). The ‘616 application only speculates that homocysteinylated albumin may be used in place of homocysteinylaed transthyretin in an immunoassay (see, for instance, paragraphs [0006] and [0008]), and an antibody to a cysteinylated albumin protein is never described. Accordingly, Applicants contend that the ‘616 publication does not anticipate the claims, as amended, because the ‘616 publication neither teaches nor suggests an antibody that specifically binds to a cysteinylated albumin protein, and therefore, withdrawal of this rejection is respectfully requested.

Conclusion

Applicants submit that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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